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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/784,720 | 02/15/2001 | Klaus Abraham-Fuchs | P00,1222 | 2613 |

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| EXAMINER | |
|---|---|
| MORAN, MARJORIE A | |
| ART UNIT | PAPER NUMBER |
| 1631 | |

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/784,720 | ABRAHAM-FUCHS ET AL. | |
| | Examiner | Art Unit | |
| | Marjorie A. Moran | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

In view of the persuasive arguments with regard to new matter and enablement set forth in the appeal brief filed on 5/15/06, PROSECUTION IS HEREBY REOPENED. New rejections are set forth below. All rejections not reiterated below are hereby withdrawn.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites devices "receiving" and "performing diagnostic testing" and recites an expert system "to which ...data is entered" and also recites an evaluation system "creating a modified expert rule..." All of these appear to be method steps, but it is noted that the claim is directed to a network (product). As it is unclear what limitations of the product is intended by any one and/or the plurality of method steps recited, the claim is indefinite.

Claims 17 and 18 recite the term "improved" in the last paragraph of each claim. The term "improved" in claims 17 and 18 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In response to applicant's arguments, filed in the appeal brief of 5/15/06, that one skilled in the art would "is fully capable of determining" (i.e. would know HOW to determine) when a diagnostic result is "improved," it is noted that the rejection is not one of enablement, but of indefiniteness. Further, it is still unclear how much better a diagnostic value must be to be considered "improved." It is also unclear what the improvement in intended to be relative TO (i,e, improved as compared to what?). As the metes and bounds *intended by applicant* for this term are still unclear, the examiner maintains that the claim is indefinite.

Claim 2 recites that an expert evaluation system "uses" a modified expert rule to "devise" a protocol. Claim 3 recites that an expert system "devises" a protocol. The term "use" and "devise" are method steps, but parent claim 17 is directed to a product.

As it is unclear what limitation of the product is intended by recitation of method steps, the claim is indefinite. It is further unclear what step or steps are intended to be encompassed by the term "uses.:

Claim 5 recites that each point of care device "accesses" a memory. Claim 6 recites that a protocol "employs" a certain number of markers. Claim 7 recites that each point of care device "conducts said diagnostic testing," "Accessing", "employing" and "conducting" diagnostic testing are all method steps, but parent claim 17 is directed to a product. As it is unclear what limitation of the product is intended by recitation of method steps, the claim is indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by KLEINSCHMIDT et al. (US 6,454,709, filed 8/29/2000).

KLEINSCHMIDT teaches use of disposable biochips in point of care devices (col. 3, lines 15-20), wherein the data from such point of care devices is transmitted to a remote server comprising an evaluation system and an expert system, evaluated, a diagnosis made, and information sent back (col. 4, lines 26-62 and Figure 1). The "expert system" must inherently comprise "expert rules" in order to evaluate the data received and make a diagnosis. KLEINSCHMIDT further teaches that information sent back may include success rates, compatibility, and side effects; interpreted to be "improved" diagnostic information, thus claim 17 is anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-7, 9-15, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over BARNHILL et al (US 6,248,063, filed 7/25/1995) in view of WRIGHT, JR (US 2004/0018519, filed 11/20/2000).

Claims 17 and 18 are directed to a network (system product) and a method of use of the network product wherein the network comprises a plurality of biochips, each comprising multiple biomolecular markers and a patient sample, a plurality of point of care devices at a plurality of sites wherein each point of care devices is capable of receiving a biochip and performing diagnostic testing on the sample to obtain raw point of care data, an expert system into which the raw data is entered, a plurality of patient records for each patient, a plurality of point of care entry stations comprising means for entering follow-up diagnostic data, a remote server and evaluation station wherein the remote server comprises data links to the point of care test devices and electronic patient records, and an evaluation system for creating a modified expert rule with improved diagnostic value.

Claims 2 and 10 limit the creation of a modified expert rule to creating one for devising a measurement protocol. Claims 3 and 11 limit the measurement protocol to be one for a selected pathology. Claims 4 and 12 limit the creating of a modified rule to be automatic. Claims 5 and 13 limit the network to comprise a memory comprising a plurality of measurement protocols and limit the point of care device to one capable of accessing the memory to obtain a selected measurement protocol. Claims 6 and 14 limit the measured protocol to be one for a specific pathology and to employ a predetermined number of biomolecular markers. Claims 7 and 15 limit the biochips to

be sensitive for more markers than are predetermined, such that augmented testing data may be obtained and included in the point of care data. Claim 8 limits the point of care data entry stations to comprise means for entering patient history data and characterization of result as false positive, false negative or correct. Claim 16 limits ht method to one further comprising obtaining follow-up data and indicating whether a test result is a false positive, a false negative or correct.

BARNHILL teaches a system and method for receiving patient data from a remote location (point of care), analyzing the data and producing a diagnostic value (abstract). BARNHILL teaches collecting patient data, including electronic patient records, , inputting the data into a neural network (remote server with evaluation system), and creating a "modified expert rule" (i.e. trained neural net) for diagnosing any of a variety of diseases, such as osteoporosis or cancer (col. 7, line 39-col. 9, line 53). BARNHILL specifically teaches that diagnostic data may be added to other raw input variables to provide a final diagnostic index; i.e. modified rule (col. 13, line 60-col. 14, line 10). BARNHILL teaches that concentrations of biomarkers are determined for a patient (col. 13, lines 11-14), and teaches that his system comprises diagnostic devices comprising sample collection means and sample detecting means (col. 14, lines 55-63), but does not specifically teach a biochip or measurement protocols.

WRIGHT teaches an integrated system and method for diagnosing prostate cancer comprising a biochip comprising prostate cancer markers, various measurement protocols, and a computer comprising instructions for determining correlations between

the markers and diagnosis (abstract and para's 26 and 28). WRIGHTE teaches that his biochips may comprise more markers than the "predetermined" ones of PSMA and PSMA' (para's 76- 78). WRIGHT teaches that his computer instruction for diagnosis may include a neural network (para 20).

It would have been obvious to one of ordinary skill in the art at the time of invention to have used the biochips and measurement protocols of WRIGHT in the system and method of BARNHILL where the motivation would have been to accurately diagnose prostate cancer and BPH using a combination of biomarkers and computer algorithms, as taught by both BARNHILL and WRIGHT.

Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over BARNHILL et al (US 6,248,063, filed 7/25/1995) in view of WRIGHT, JR (US 2004/0018519, filed 11/20/2000).as applied to claims 2-7, 9-15, and 17-18 above, and further in view of KULIKOWSKI et al. (Proc. Of ACM Conference on History of Medical Informatics. Dec. 1987, pp. 199-206).

BARNHILL and WRIGHT make obvious a system and method of diagnosing a disease by collecting data and analyzing a patient sample using a biochip in a point of care, transmitting that data via a network to a remote server, performing a diagnosis using an expert system/rules, and updating or modifying the expert system based on new information received. BARNHILL and WRIGHT do not specifically teach entering or gathering further patient data to determine whether a diagnosis is false or correct.

KULIKOWSKI, throughout his papers stress the importance of computerized "expert rule"-base diagnoses "matching" diagnoses by human experts, and specifically teaches that one rule-based program matched the diagnostic conclusions of specialists in the field (p. 204).

It would have been obvious to one of ordinary skill in the art at the time of invention to have compared the computerized diagnosis of the expert system in the method and system of BARNHILL and WRIGHT to diagnosis by human experts following receipt of the computerized results in order to determine "true" positive or negative results, as taught by KULIKOWSKI, where the motivation would have been to confirm the computerized diagnosis, as suggested by KULIKOWSKI's repeated comparisons between computerized expert rules and human experts.

***Conclusion***

Claims 2-18 are rejected.

The prior art made of record and not relied upon which is considered pertinent to applicant's disclosure is:.

SU, Mu-Chun. Computers in Biology and Medicine. 1994. Volume 24, no.6, pp. 419-429, who teaches expert systems for medical diagnosis;

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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